

**Remarks**

By this amendment, claims 1, 2, 4, and 5 are amended. The amendments are made to even more clearly define the claimed invention and do not add new matter. Reconsideration of the rejected claims in view of the above amendments and the following remarks is respectfully requested.

**Claim Rejections – 35 U.S.C. § 112, First Paragraph**

The Office Action rejects claims 1-8 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirements. Specifically, the Examiner alleges that the scope of the claims is overbroad due to the recitation of “deletion, substitution, or addition of one to thirty nucleotides” to SEQ ID Nos. 1-4. Based on the Examiner’s interpretation of this recitation, the Examiner asserts that it is not clear whether multiple regions of thirty nucleotides may be deleted, and which thirty base pairs may be modified.

In response, Applicants submit that the specification teaches methods for introducing mutations to the claimed nucleotide sequences, and recommends against introducing mutations to particular regions of the claimed sequences, which enhance gene expression efficiency in motor neurons (*see, e.g.*, page 9, paragraph 4, through page 10, paragraph 1, of the specification). Furthermore, the homologous sequences are clearly described in the specification, along with the location of these sequences within SEQ ID NOS. 1-6 (*see, e.g.*, page 10, paragraph 1).

The claims are also expressly directed to sequences, which are “capable of enhancing gene expression efficiency in motor neurons.” Thus, the claims exclude mutations which would not be “capable of enhancing gene expression efficiency in motor neurons.” Based on the description of nucleotide mutations in the specification and the claims, Applicants submit that one skilled in the art would be convinced that the Applicants were in possession of the claimed invention.

The Examiner also asserts that 1) the sequences set forth in SEQ ID NOs 1-6 are not representative of the broad genus claimed because they do not convey the necessary common attributes or features of essentially any nucleic acid having the same function; and 2) the specification provides no disclosure of the structural features that define the function recited in the claims.

Applicants respectfully disagree. Applicants note that the specification clearly describes the common features or areas of homology between SEQ IDs 1-6 (see, e.g., page 10, lines 2-20, in the specification) and their common function. The specification indicates that

[t]he region between nucleotides 235 and 560 of SEQ ID NO: 1, the region between nucleotides 204 and 528 of SEQ ID NO: 2, the region between nucleotides 206 and 530 of SEQ ID NO: 3, and the region between nucleotides 211 and 555 of SEQ ID NO: 4 are highly homologous to one another and are highly conserved among species. Accordingly, it is suggested that these regions of SEQ ID NOs: 1 to 4 **contribute to functions of enhancers for improving gene expression efficiency in motor neurons**. The region between nucleotides 378 and 553 of SEQ ID NO: 5 and the region between nucleotides 178 and 353 of SEQ ID NO: 6 are highly homologous to each other and are highly conserved among species. Accordingly, it is suggested that these regions of SEQ ID NOs: 5 and 6 **contribute to functions of enhancers for improving gene expression efficiency** in sensory neurons and/or in motor neurons that extend axons ventrally. (emphasis added)

The specification clearly asserts that these areas of homology function as “enhancers for improving gene expression efficiency in motor neurons,” thereby establishing a common feature with an associated common function among these sequences.

Furthermore, as discussed above, the claims require that the claimed sequences are “capable of enhancing gene expression efficiency in motor neurons.” The specification also recommends against introducing mutations to particular regions of the claimed sequences (which enhance gene expression efficiency in motor neurons), which would produce sequences that are not capable of enhancing gene expression efficiency in motor neurons. Accordingly, Applicants submit that the specification and claims describe the common function of the claimed genus of sequences. Furthermore, as discussed above, the specification describes the common structure of the claimed genus of sequences by describing the regions of homology in SEQ ID NOs. 1-6, and the location of these homologous regions within SEQ ID NOs. 1-6 (*see, e.g.*, page 10, paragraph 1).

Thus, one skilled in the art would appreciate the common structural features of the claimed genus of sequences, and would be convinced that the Applicants were indeed in possession of the claimed invention at the time of filing. Accordingly, Applicants submit that that the specification sufficiently describes the common structural features that the specification sufficiently defines the function recited in the claims, thereby clearly defining the claimed genus of sequences.

Accordingly, Applicants respectfully request that the rejection be withdrawn.

#### **Claim Rejections – 35 U.S.C. § 112, Second Paragraph**

The Office Action rejects claims 1, 2, 4, and 5 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Examiner asserts that the phrase “stringent conditions” (recited in element (c) of claims 1, 2, 4, and 5) is indefinite, alleging that neither the claims nor the specification define this term.

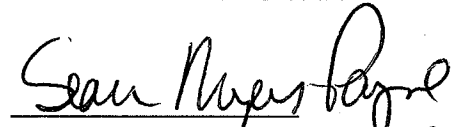
Without agreeing with or acquiescing to the rejection, Applicants note that claims 1, 2, 4,

and 5 have been amended to remove element (c). Applicants respectfully request withdrawal of the rejection.

### Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of all outstanding rejections, and an indication of the allowability of all claims pending in the present application in due course. Should the Examiner have any questions or comments regarding this response, or the present application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,  
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